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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,580	06/26/2003	Roberto C. Beretta	019492-9038-01	5786

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EXAMINER	
HANLEY, SUSAN MARIE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,580	BERETTA ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,20-22,24,25,27-32 and 34-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,20-22,24,25,27-32 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/20/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The indicated allowability of claims 32 and 34-41 is withdrawn.

Claim Rejections - 35 USC § 112

Claims 18, 20-22, 24, 25, 27-32 and 34-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a device for axial centrifugation. The common feature of the independent claims is that the device comprises a primary chamber, a secondary chamber containing a coagulator, and a medium that separates the primary and secondary chamber wherein the medium is a separation medium is a silicone gel, a thixotropic gel or a polyester gel. The medium comprises a filter (claim 22). The medium is the only thing that separates the two chambers. The common feature of said independent claims is New Matter because the claimed invention is not commensurate in scope compared to what is disclosed in the specification.

According to the first embodiment, the primary chamber and the secondary chamber are separate entities (e.g., tubes), see Figures 1. The secondary chamber contains the coagulant. The primary chamber contains the separation medium 26, that is a thixotropic gel (page 20, lines 33-34). Blood is drawn into the primary chamber 10 that can have an anti-coagulant. The primary tube is centrifuged (page 13, lines 27-33). The result is that the centrifugation results in a plurality of layers see Fig 2, wherein the

of container 10 contains from the bottom, the red blood cells (RBCs), the separation medium and the platelet-rich plasma layer, the LDHV fluid layer and then and the residual gas (page 14, lines 1-7 and Fig. 2). There is no mention of a coagulant in the primary chamber that contains said separator. The inversion of the tube 10 (Fig. 7) inverts the order in which the layers are arranged such that the platelet-rich layer is above the seal and the RBCs are above the separation medium (page 14, lines 9-15). The primary chamber and the secondary chamber are brought together and punctured by a transfer device (page 14, lines 20-33) such that the plasma is transferred to the secondary chamber (page 15, lines 11-12). The transfer of the platelet-rich plasma is complete when the LDHV fluid plugs the transfer device (a cannula; page 15, line 20). Then the transferred platelet-rich plasma (PRP) reacts with the coagulator in the secondary chamber to form a solid-fibrin web (page 15, lines 24-27). This disclosure does not teach a single chamber or tube that is divided by a separation medium such that there is a primary and secondary chamber wherein the secondary chamber contains a coagulant. According to the indicated disclosure the primary and secondary chambers are different tubes and the primary chamber contains only a separation medium that effects the separation of the RBCs and the platelet-rich plasma fraction. There is no inclusion of a coagulant in a portion of the primary chamber that is divided by a separation medium.

It is noted that claim 37 is directed to the separation of the primary chamber into an upper and lower portion by a medium that substantially prevents fluid communication there between but that fluid communication is provided between the upper and lower

portions when the device is centrifuged about 1000 x G or greater. Again, this arrangement is not disclosed because the specification does not teach that the primary and secondary chamber are separated by a silicone gel, a thixotropic gel or a polyester gel, that is further subdivided by a second separation medium.

The specification discloses another embodiment that is also narrow than the generically claimed New Matter. The device shown in Figs. 21-25 comprises two chambers. The upper or primary chamber acts as the cell separation chamber while the secondary or lower chamber acts as the densification chamber. A diaphragm separates the two chambers. Fluid communication us provided by vents that are plugged with a separation medium that is one of a silicone gel, a thixotropic gel or a polyester gel. The primary chamber receives blood from the patient. The primary chamber can contain an anti-coagulant. The secondary chamber can contain a coagulating activator and a therapeutic secondary substance (page 27, lines 15-28).

After collection of the blood, the device is centrifuged to effect cell separation. As seen in Fig 22, the gel will maintain separation of the two chambers during the filling step but will move outwardly and upwardly to separate the RBCs and the PRP. The PRP will drain through the vents into the secondary chamber where it is mixed with the clot activator (page 28, lines 1-20). Again, this embodiment is narrower in scope with that that which is claimed.

In independent claim 22, the separation medium comprises a filter. This is New Matter because the specification does not teach that the separation medium comprises a filter. According to Jahn (US 5,275,731; previously cited) thixotropic gels perform do

not perform significant filtering action on the blood samples (col. 27, lines 27-30). Therefore, the gels are not inherently filters.

Therefore, the claims are rejected because there is no disclosure that is commensurate in scope with the broadly claimed invention wherein the claims are drawn to a device for axial centrifugation wherein the common feature of the independent claims is that the device comprises a primary chamber, a secondary chamber containing a coagulator, and that only a medium separates the primary and secondary chamber wherein the medium is a separation medium is a silicone gel, a thixotropic gel or a polyester gel. The disclosure of the two embodiments discussed supra is narrower than that which is claimed. In one embodiment, the primary chamber and the secondary chamber are two separate tubes and the primary chamber contains only the separation medium. The secondary chamber contains only the coagulant. In the second mentioned embodiment, a diaphragm plugged with a gel separates the two chambers. Any embodiments that fall outside of said embodiments but within the scope of the claimed subject matter constitutes New Matter.

Terminal Disclaimer

The terminal disclaimers filed on 04/28/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Application No. 12/424,317 and US Patent No. 6,979,307 has been reviewed and is accepted. The terminal disclaimers have been recorded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Susan Hanley/
Examiner, Art Unit 1651